Frederick National Laboratory for Cancer Research sponsored by the National Cancer Institute	Vaccine, Immunity and o Standard Operation				
SOP Title: Use and Maintenance of a 2-8°C Refrigerator					
Document ID: 26005	Version	3.0			
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Effective Date: 17Sep21					

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1. PURPOSE

1.1. The purpose of this procedure is to describe the proper use and handling of a 2-8°C Refrigerator.

2. SCOPE

2.1. This procedure applies to all laboratory refrigerator units.

3. REFERENCES

- 3.1. Laboratory Refrigerator User Manual
- 3.2. 26005-01: 2-8°C Refrigerator Maintenance Form
- 3.3. 26005-02: 2-8°C Refrigerator Temperature Monitor Log Form
- 3.4. 10007-01: Non-Routine Equipment Maintenance Form
- 3.5. 15000: Waste Disposal at the Advanced Technology Research Facility

4. RESPONSIBILITIES

- 4.1. The Research Associate, hereafter referred to as Analyst, is responsible for reviewing and following this procedure, and documenting performance of equipment maintenance.
- 4.2. The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.
- 4.3. The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.
- 4.4. Trained personnel perform equipment maintenance record review per "10009: General Record Review."

5. REAGENTS, CHEMICALS AND EQUIPMENT

- 5.1. Primary Disinfectant (Cavicide, FNLCR Warehouse, Cat # 79300360 or equivalent)
- 5.2. Revco 2-8°C Refrigerator or equivalent.
- 5.3. Secondary Disinfectant (Ster-ahol, VWR, Cat # 14003-358 or equivalent)
- 5.4. Wipe, Low-Lint, Wypalls (FNLCR Warehouse, Cat # 79300335 or equivalent)

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6. HEALTH AND SAFETY CONSIDERATIONS

- 6.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.
- 6.2. Refer to the respective SDS when working with any chemicals.
- 6.3. Refer to "15000: Waste Disposal at the Advanced Technology Research Facility" regarding waste disposal processes at the ATRF.

7. **DEFINITIONS**

- 7.1. °C Degree Centigrade
- 7.2. As Needed Maintenance maintenance that is performed outside of routine maintenance but is not performed in response to equipment malfunction.
- 7.3. Non-Routine Maintenance maintenance that is performed in response to equipment malfunction or failure.
- 7.4. REES Rees Scientific is a provider of automated temperature monitoring systems.

8. OPERATION

- 8.1. Start-up
 - 8.1.1. Connect power cord to outlet.
 - 8.1.2. Insert key into switch and turn power on.

Note: Rotate power switch to ALARM ON position once temperature drops below the warm alarm set-point. See 8.1.4.

- 8.1.3. Allow unit to reach operating temperature before loading it with any product. To stabilize the temperature profile, a 24-hour waiting period is recommended.
- 8.1.4. After unit has pulled down to desired operating temperature, turn three-position key switch one turn further clockwise to Alarm On position.
- 8.1.5. If a remote alarm required, hook it up at this point.
- 8.1.6. Alarm set-points are factory pre-set for 5.5°C (warm) and 1.5°C (cold).

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Note: If refrigerator is set-up with REES alarm system, it is maintained by FME. See Section 8.5.

8.2. Use

- 8.2.1. Do not leave doors open for extended periods of time.
- 8.2.2. If a spill occurs, wipe down and clean with appropriate cleaner. See 8.3.1.
- 8.2.3. If a refrigerator is not on the REES Monitoring system, Daily Temperature is recorded on business days on "26005-02: 2-8°C Refrigerator Temperature Monitor Log Form."
 - 8.2.3.1. Reset digital thermometer prior to periods when a daily temperature log is not achievable (holidays, weekends) and record temperature min and max for the missed days. Add an asterisk (*) to the "Actual Temp" cell during holidays and weekends when the actual temperature is not recorded on the same day.

8.3. As Needed Maintenance

- 8.3.1. If a spill occurs, wipe down and clean with Cavicide.
- 8.3.2. Record event on "26005-01: 2-8°C Refrigerator Maintenance Form."

8.4. Annual Maintenance

- 8.4.1. Turn off unit.
- 8.4.2. Remove all contents within the refrigerator.
- 8.4.3. Spray internal unit with Cavicide and wipe with a clean low-lint wipe.
- 8.4.4. Turn unit on and allow it to stabilize between 2-8°C, then return contents to the refrigerator.
- 8.4.5. Document maintenance performed on HSL_EQ_007.01: 2-8°C Refrigerator Use and Maintenance Form.

8.5. Annual Calibration

8.5.1. Facilities, Maintenance, and Engineering (FME) or a contracted vendor shall perform annual calibration of the 2-8°C Refrigerator, if required.

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8.5.2. Document maintenance performed on 26005-01.

8.6. Non-Routine Maintenance

- 8.6.1. In the case that the refrigerator is not operating correctly, transition processes being performed to another unit (when applicable), post a sign stating the equipment is out of service and initiate non-routine maintenance documentation per "10007: Non-Routine Equipment Maintenance."
- 8.6.2. Document the nature of any failures or malfunctions, how and when it was discovered, and the personnel involved on "10007-01: Non-Routine Equipment Maintenance Form."
- 8.6.3. Initiate a service request and complete the non-routine maintenance process following 10007.

9. SETTINGS

- 9.1. Temperature Range: 2°C to 8°C
- 9.2. Out of Range Events
 - 9.2.1. If the instrument maintains a temperature out of range for more than 0.5 hours, then transfer biological contents to another unit. Initiate non-routine maintenance per section 8.6.
- 9.3. REES monitoring
 - 9.3.1. If REES temperature monitoring system used, the system will monitor refrigerator temperature range of 2°C to 8°C.
 - 9.3.2. Temperature range will be monitored at: 2°C to 8°C.
 - 9.3.3. Out of Range Events
 - 9.3.3.1. If REES system or refrigerator unit goes into alarm, acknowledge alarm by emailing the laboratory personnel and log-in to the REES system to inhibit refrigerator for no more than 0.5 hours.
 - 9.3.3.1.1 If refrigerator maintains temperature out of range for more than 0.5 hours, then transfer contents to another refrigerator.
 - 9.3.3.1.1 Initiate non-routine maintenance per 8.6.

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10. ATTACHMENTS

- 10.1. Attachment 1: 26005-01: 2-8°C Refrigerator Maintenance Form.
- 10.2. Attachment 2: 26005-02: 2-8°C Refrigerator Temperature Monitor Log Form.

11. REVISION HISTORY

Version #	Changes	Reasons
1.0	Create new SOP for use and maintenance of 2-8°C refrigerator	Currently no SOP
2.0	Remove Date column from form .02.	Redundant.
3.0	Added Non-Routine and As Needed Maintenance Added Settings Section	Reflect current guidelines Clarity
	Updated Reference Section Updated Forms	3) Reflect current naming schema4) Reflect current guidelines

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Attachment 1: 26005-01: 2-8°C Refrigerator Maintenance Form

Frederick National Laboratory for Cancer Research sponsored by the National Cancer Institute			Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Form				
Form Title: Refrigerate	or Maintenance Fo	orm					
Document ID: 26005-01 Version: 3.0)			
Associated SOP: 26005	5		Effe	ctive Date:		17Sep21	
Supersedes Version:		2.0			Page 1 c	of 1	
Equipment I	D:			Maintenance Year:			
Annual Maintenance:							
Cavicide Lot Num	nber:						
Cavicide Expiration	Date:]			
Performed by/da	ate:						
Reviewed by/da	2:						
Reviewed by/da	nte:						
As Needed Maintenanc							
•		Activity Performe	d		Perform	ned by/date	Reviewed by/date
As Needed Maintenanc		Activity Performe	d		Perform	ned by/date	Reviewed by/date
As Needed Maintenanc		Activity Performe	d		Perform	ned by/date	Reviewed by/date
As Needed Maintenanc Date		Activity Performe	d		Perform	ned by/date	Reviewed by/date
As Needed Maintenanc Date		Activity Performe	d		Perform	ned by/date	Reviewed by/date
As Needed Maintenanc Date	e: □ N/A	Activity Performe	d		Perform	ned by/date	Reviewed by/date
As Needed Maintenanc Date II N/A	e: N/A	Activity Performe	_	r obsolete document			Reviewed by/date

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Attachment 2: 26005-02: 2-8°C Refrigerator Temperature Monitor Log Form

Frederick National Laboratory for Cancer Research sponsored by the National Cancer Institute		Vacci	Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Form		
Form Title: Refrigerator Tem	perature Monitor Log I	Form			
Document ID: 26005-02	Versi	on:	3.0 17Sep21		
Associated SOP: 26005	Effective	Date:			
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Month / Year		Equipment ID:	:		
Thermometer Serial #: Day Actual Temp (°C) Min 1	emp (°C) Max Temp (°C)	Analyst Initials	Temperature	Range: 2°C to 8°C Comments	
EN/A 1	emp (c) wax remp (c)	Alalyst Ilitials	IN/A Them	234 1985	
EN/A 2			□N/A □ Thermometer reset □N/A □ Thermometer reset		
EN/A 3		□N/A □ Thermometer reset			
□N/A 4			□N/A □ Thermometer reset		
⊥ N/A 5			IN/A Thermometer reset		
□N/A 6		□N/A □ Thermometer reset			
□N/A 7			□N/A □ Thermometer reset		
□N/A 8			□N/A □ Thermometer reset		
□N/A 9		□N/A □ Thermometer reset			
□N/A 10		□N/A □ Thermometer reset			
I N/A 11		IN/A Thermometer reset			
□N/A 12		□N/A □ Thermometer reset			
□N/A 13		□N/A □ Thermometer reset			
□N/A 14			□N/A □ Thermometer reset		
□N/A 15		1	□N/A □ Thermometer reset		
□N/A 16			□N/A □ Thermometer reset		
□N/A 17			□N/A □ Thermometer reset		
□N/A 18		□N/A □ Thermometer reset			
□N/A 19 □N/A 20		□N/A □ Thermometer reset			
□N/A 21		IN/A Thermometer reset			
□N/A 22		□N/A □ Thermometer reset			
□N/A 23		□N/A □ Thermometer reset			
□N/A 24		□N/A □ Thermometer reset			
□N/A 25		□N/A □ Thermometer reset			
□N/A 26		□N/A □ Thermometer reset			
□N/A 27			□N/A □ Therm		
□N/A 28			□N/A □ Therm	nometer reset	
□N/A 29			□N/A □ Therr	nometer reset	
□N/A 30			□N/A □ Therm	nometer reset	
□N/A 31			□N/A □ Therm	nometer reset	

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Supersedes:	2.0	Pa	age 2 of 2	
QA Reviewed by/date: _				

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